

August 8, 2002

Mr. Nigel J. Sarginson
Product Stewardship & Regulatory Affairs Manager
ExxonMobil Chemical Company
13501 Katy Freeway
Houston, TX 77079

Dear Mr. Sarginson:

We have conducted an initial review of the Olefin Hydroformylation Products category submitted by ExxonMobil Chemical Company as part of their commitment under the HPV Challenge Program.

Our preliminary analysis focused on the overall approach including the category definition and description. We have concluded that, while the category proposal may be feasible, EPA is unable to continue its evaluation for the following reasons.

1. The test plan states that products in this category are "alkyl alcohol bottoms" composed of olefins and alkyl alcohols that are residual waste materials from the production of alkyl alcohols from olefins by hydroformylation. However, the terms "alkyl alcohol bottoms" and "residual waste materials" seem inconsistent with materials that contain only olefins and alcohols. The terms imply the residues remaining after distillation of the desired products and are consistent with a complex mixture of by-products.

The expectation that these substances are complex mixtures is also consistent with the NLM ChemID definitions of the CAS numbers used for the category members. For example, for three of the CAS numbers cited in the submission, 70955-11-2 (hexene, HOF), 70955-03-2 (hexene, HOF, low-boiling), and 70955-04-3 (hexene, HOF, high-boiling), the ChemID definitions as a group mention C6 olefins and paraffins, C7 alcohols, aldehydes, acetals, C7-8 primary aliphatic alcohols, C12-16 dimer alcohols, C14 acetals and esters and C10 acid sodium salts. Given the range of possible constituents, the test plan needs to provide more information to characterize the sponsored substances and/or explain why and how they differ from the CAS number definitions.

2. The submission contains no listing of the percent composition or composition ranges even for the alcohol and olefin constituents the company acknowledges are present. This seriously hinders an effective evaluation of the proposal.

3. Similarly, none of the robust summaries, many of which are for studies on mixtures, state the percentage composition of the test material.

4. The company did not submit robust summaries for some studies cited in the test plan. The missing summaries are identified below.

1-Hexanol: Mutagenicity study (p 14, test plan) – cited as "available from IUCLID"

Subchronic feeding study (p 17, test plan) – cited as "available from IUCLID"

2-Ethylhexanol: Subchronic gavage study (p 17, test plan) – cited as "available from IUCLID"

1-Dodecanol: Acute toxicity study (Table 4, test plan)

No robust summaries were submitted for the ECOSAR estimations or for most physicochemical properties.

Because robust summaries must be available to the public, the submission must include adequate summaries for all studies and estimation results. Moreover, IUCLID summaries often need additional information before they can qualify as adequate robust summaries.

5. Poor coordination among parts of the submission unnecessarily burdens reviewers. For example, a repeated-dose study on “alcohols, C11-C14 iso, C13-rich”, is referenced in Table 4 as “C13-C14 alcohol”, and a study on “C7-9-11 alcohol” is lumped with another study in Table 4 under “C11 alcohol.” Study results quoted in the biodegradation table are not cross-referenced to specific robust summaries (a problem because the CAS numbers do not match).

6. Table 2 in the Test Plan omits data for log P.

I encourage ExxonMobil to take the necessary steps to enhance the submission. We are prepared to proceed to data adequacy determinations as soon as we get your response.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site “Submit Technical Questions” button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber